INTERNATIONAL STANDARD

ISO 7870-1

> Third edition 2019-11

rart 1:

General guidelines

Cartes de contrôle —

Partie 1: Lignes direc

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee SO/TC 69, *Applications of statistical methods*, Subcommittee SC 4, *Applications of statistical methods in process management*.

This third edition of ISO 7870-1 cancels and replaces the second edition (ISO 7870-1:2014), which has been technically revised.

The main changes compared to the previous edition are as follows:

Added Annex A, specifying the conventions for drafting control charts.

A list of all parts in the ISO 7870 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Every production, service, or administrative process contains a certain amount of variability due to the presence of a large number of causes. The observed results from a process are, as a result, not constant. Studying this variability to gain an understanding of its characteristics provides a basis for taking action on a process.

Control charts are a fundamental tool of statistical process control (SPC). They provide a simple graphical method that can be used to

- a) indicate if the process is stable, i.e. operating within a stable system of random causes, also known as inherent variability and referred to as being in a "state of statistical control",
- b) estimate the magnitude of the inherent variability of the process,
- c) compare information from samples representing the current state of a process against control limits reflecting this variability, with the objective of determining whether the process variability has remained stable or is reduced or increased.
- d) identify, investigate, and possibly reduce/eliminate the effect of special causes of variability, which can drive the process to an unacceptable level of performance,
- e) aid in the regulation of a process through the identification of patterns of variability such as trends, runs, cycles, etc.,
- f) determine if the process is behaving in a predictable and stable manner so that it will be possible to assess if the process is able to meet specifications.
- g) determine whether or not the process can be expected to satisfy product or service requirements and process capability for the characteristic(s) being measured,
- h) provide a basis for process adjustment through prediction using statistical models, and
- i) assist in the assessment of the performance of a measurement system.

A major virtue of the control chart is its ease of construction and use. It provides the production or service operator, engineer, administrator, and manager with an online indicator about the behaviour of the process. However, in order for the control chart to be a reliable and efficient indicator of the state of the process, careful attention has to be paid at the planning stage to such matters as selecting the appropriate type of chart for the process under study and determining a proper sampling scheme.

General concepts useful to a successful design of a control chart are presented in Annex A.

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Control charts —

Part 1:

General guidelines

1 Scope

This document presents key elements and the philosophy of the control chart approach, and identifies a wide variety of control charts (including those related to the Shewhart control chart, those stressing process acceptance or online process adjustment, and specialized control charts)

It presents an overview of the basic principles and concepts of control charts and illustrates the relationship among various control chart approaches to aid in the selection of the most appropriate part of ISO 7870 for given circumstances. It does not specify statistical control methods using control charts. These methods are specified in the relevant parts of ISO 7870.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3534-1, Statistics — Vocabulary and symbols — Part 1: General statistical terms and terms used in probability

ISO 3534-2, Statistics — Vocabulary and symbols — Part 2: Applied statistics

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3534-1, ISO 3534-2 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at https://www.iso.org/obp
- IEC Electropedia: available at http://www.electropedia.org/

3.1

controlchart

chart with $control\ limits\ (3.2)$ on which some statistical measure of a series of samples is plotted in a particular order to steer the process with respect to that measure

Note 1 to entry: The particular order is usually based on time or sample number order.

Note 2 to entry: The control chart operates most effectively when the measure is a process variable which is correlated with an ultimate product or service characteristic.

[SOURCE: ISO 3534-2:2006, 2.3.1, modified — added "with control limits" after "chart" in definition, deleted "and to control and reduce variation" after "to that measure".]

control limit

statistical value defining an intended level of stability for a produced characteristic

Note 1 to entry: One or two control limits are represented on the control chart.

Note 2 to entry: The term "stability" is not meant only for a process in control but it can also be stability against a target value.

3.3

Shewhart control chart

control chart (3.1) with Shewhart control limits (3.4) intended primarily to distinguish between the variation in the plotted measure due to random causes and that due to special causes

[SOURCE: ISO 3534-2:2006, 2.3.2]

3.4

Shewhart control limit

control limit (3.2) determined statistically from the variation of the process due to the random causes alone

3.5

acceptance control chart

control chart (3.1) intended primarily to evaluate whether or not the plotted measure can be expected to satisfy specified tolerances

[SOURCE: ISO 3534-2:2006, 2.3.3]

3.6

process adjustment control chart

control chart (3.1) which uses a prediction model of the process to estimate and plot the future course of the process if no change is made, and to quantify the change to be made to keep the process deviations within acceptable limits

[SOURCE: ISO 3534-2:2006, 2.3.4]

3.7

variables control chart

control chart (3.1) in which the measure plotted represents data on a continuous scale

[SOURCE: ISO 3534-2:2006, 2:3.6, modified — deleted "Shewhart" before "control chart".]

3.8

attributes control chart

control chart (3.1) in which the measure plotted represents countable or categorized data

[SOURCE: ISO 3534-2:2006, 2.3.7, modified — in the term, "attributes" used instead of "attribute"; in the definition, deleted "Shewhart" before "control chart".]

3.9

c chart

count control chart

attributes control chart (3.8) for the number of incidences where the opportunity for occurrence is fixed

Note 1 to entry: Incidences of a particular type, for example, number of absentees and number of sales leads, form the count. In the quality field, incidences are often expressed as nonconformities and the fixed opportunity relates to samples of constant size or fixed amount of material. Examples are "flaws in each 100 m^2 of fabric" and "errors in each 100 invoices".

[SOURCE: ISO 3534-2:2006, 2.3.8]

u chart

count per unit control chart

attributes control chart (3.8) for the number of incidences per unit where the opportunity is variable

Note 1 to entry: Incidences of a particular type, for example, number of absentees and number of sales leads, form the count. In the quality field, incidences are often expressed as nonconformities and the variable opportunity relates to subgroups of variable size or variable amounts of material.

[SOURCE: ISO 3534-2:2006, 2.3.9]

3.11

np chart

number of categorized units control chart

attributes control chart (3.8) for number of units of a given classification where the subgroup size is constant

Note 1 to entry: In the quality field, the classification usually takes the form of "nonconforming units".

[SOURCE: ISO 3534-2:2006, 2.3.10, modified — definition uses "subgroup" instead of "sample".]

3.12

p chart

proportion categorized units control chart

percent categorized units control chart

attributes control chart (3.8) for number of units of a given classification per total number of units in the sample expressed either as a proportion or percent

Note 1 to entry: In the quality field, the classification usually takes the form of "nonconforming unit".

Note 2 to entry: The *p* chart is applied particularly when the subgroup size is variable.

Note 3 to entry: The plotted measure can be expressed as a proportion or as a percentage.

[SOURCE: ISO 3534-2:2006, 2.3.11]

3.13

standardized p chart

attributes control chart (3.8) where proportions of given classification are expressed as standardized normal variates

3.14

X bar control chart

average control chart

variables control chart (3.7) for evaluating the process level in terms of subgroup averages

[SOURCE: VSO 3534-2:2006, 2.3.12]

3.15

median control chart

variables control chart (3.7) for evaluating the process level in terms of subgroup medians

[SOURCE: ISO 3534-2:2006, 2.3.13]

3 16

moving average control chart

control chart (3.1) for evaluating the process level in terms of the arithmetic average of each successive n observations

Note 1 to entry: This chart is particularly useful when only one observation per subgroup is available. Examples are process characteristics such as temperature, pressure and time.

Note 2 to entry: The current observation replaces the oldest of the latest n + 1 observations.

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Note 3 to entry: It has the disadvantage of an unweighted carry-over effect lasting *n* points.

[SOURCE: ISO 3534-2:2006, 2.3.14]

3.17

individuals control chart

X control chart

variables control chart (3.7) for evaluating the process level in terms of the individual observations in the sample

Note 1 to entry: This chart is usually accompanied by a moving range chart, frequently with n = 2.

Note 2 to entry: It sacrifices the advantages of averaging in terms of minimizing random variation and the normal distribution central limit theorem assumptions.

Note 3 to entry: Individual values are expressed by the symbols $x_1, x_2, x_3, ...$

Note 4 to entry: In the case of charts for individuals, the symbol R_{moving} represents the value of the moving range, which is the absolute value of the difference between two successive values, thus, $|x_1 - x_2|$, $|x_2 - x_3|$, etc.

[SOURCE: ISO 3534-2:2006, 2.3.15, modified — Note 3 to entry and Note 4 to entry added.]

3.18

cumulative sum control chart

CUSUM chart

control chart (3.1) where the cumulative sum of deviations of successive sample values from a reference value is plotted to detect shifts in the level of the measure plotted

Note 1 to entry: The ordinate of each plotted point represents the algebraic sum of the previous ordinate and the most recent deviation from the reference, target, or control value.

Note 2 to entry: The best discrimination of changes in level is achieved when reference value is equal to the overall average value.

Note 3 to entry: The chart can be used in control diagnostic or predictive mode.

Note 4 to entry: When used in control mode, it can be interpreted graphically by a mask (e.g. *V*-mask) superimposed on the graph. A signal occurs if the path of the CUSUM intersects or touches the boundary of the mask. Alternatively, a tabular approach to CUSUM may be used instead.

[SOURCE: ISO 3534-2:2006, 2.3.5] modified —Last sentence to Note 4 to entry added.]

3.19

EWMA control chart

exponentially weighted moving average control chart

control chart (3.1) for evaluating the process level in terms of an exponentially smoothed moving average

[SOURCE: ISO 3534-2:2006, 2.3.16]

3.20

Z chart

variables control chart (3.7) for evaluating the process in terms of subgroup standardized normal variates

3.21

group control chart for averages

variables control chart (3.7) for evaluating the process level in terms of subgroup (with several sources) highest and lowest averages with corresponding source identification

3.22

group control chart for ranges

variables control chart (3.7) for evaluating the process variation in terms of subgroup (with several sources) highest ranges with corresponding source identification

high-low control chart

variables control chart (3.7) for evaluating the process level in terms of subgroup largest and smallest values

3.24

trend control chart

control chart (3.1) for evaluating the process level with respect to the deviation of the subgroup averages from an expected change in the process level

Note 1 to entry: The trend can be determined empirically or by regression techniques.

Note 2 to entry: A trend is an upward or downward tendency, after exclusion of the random variation and cyclical effects, when observed values are plotted in the time order of the observations.

[SOURCE: ISO 3534-2:2006, 2.3.17]

3.25

R chart

range control chart

variables control chart (3.7) for evaluating variation in terms of subgroup ranges

Note 1 to entry: The value of the subgroup range is given by the symbol *R*, the difference between the largest and smallest observations of a subgroup.

Note 2 to entry: The average value of the subgroup ranges is denoted by the symbol R.

[SOURCE: ISO 3534-2:2006, 2.3.18, modified — Note 1 to entry and Note 2 to entry added.]

3.26

s chart

standard deviation control chart

variables control chart (3.7) for evaluating variation in terms of subgroup standard deviations

Note 1 to entry: The value of the subgroup standards deviation is given by the symbol s.

Note 2 to entry: The average value of the subgroup standard deviations is denoted by the symbol \overline{s} .

[SOURCE: ISO 3534-2:2006, 2.3.19, modified — Note 1 to entry and Note 2 to entry added.]

3.27

moving range control chart

variables control chart (3.7) for evaluating variation in terms of the range of each successive n observations

Note 1 to entry. The current observation replaces the oldest of the latest n + 1 observations.

[SOURCE: ISO 3534-2:2006, 2.3.20]

3.28

control chart for coefficient of variation

variables control chart (3.7) for evaluating variation in terms of subgroup coefficient of variation

3.29

multivariate control chart

control chart (3.1) in terms of the responses of two or more mutually correlated variates combined as a single sample statistic for each subgroup

[SOURCE: ISO 3534-2:2006, 2.3.21]

multiple characteristic control chart

attributes control chart (3.8) for evaluating the process level based on more than one characteristic

[SOURCE: ISO 3534-2:2006, 2.3.22, modified — "for evaluating the process level" added.]

3.31

demerit control chart quality score chart

multiple characteristic control chart (3.30) for evaluating the process level where different weights are apportioned to events depending on their perceived significance

[SOURCE: ISO 3534-2:2006, 2.3.23, modified — "for evaluating the process level" added.]

3.32

process adjustment

action to reduce the deviation from the target in the output characteristic by making appropriate compensatory changes in some other control variable by measurement of fluctuations in an input or output variable

Note 1 to entry: Ongoing monitoring determines whether the process and the system of process adjustment itself are, or are not, in a state of statistical control.

[SOURCE: ISO 3534-2:2006, 2.3.24, modified — using "by making appropriate compensatory changes in some other control variable by measurement of fluctuations in an input or output variable" instead of "by feed-forward control and/or feedback control".]

3.33

control variable

variable in the process that is varied as a function of the actuating signal so as to change the value of the process output

Note 1 to entry: Actuating signal can be triggered by measurable changes in process.

[SOURCE: ISO 3534-2:2006, 2.3.27, modified—Note 1 to entry added.]

3.34

autocorrelation

internal correlation between members of series of observations ordered in time

[SOURCE: ISO 3534-2:2006, 2:3:28]

3.35

special cause

Note 1 to entry. Sometimes "special cause" is taken to be synonymous with "assignable cause". However, a distinction is recognized. A special cause is assignable only when it is specifically identified.

Note 2 to entry: A special cause arises because of specific circumstances that are not always present. As such, in a process subject to special causes, the magnitude of the variation from time to time is unpredictable.

[SOURCE: ISO 3534-2:2006, 2.2.4]

3.36

random cause

common cause

chance cause

Note 1 to entry: In a process subject only to random cause variation, the variation is predictable within statistically established limits.

Note 2 to entry: The reduction of these causes gives rise to process improvement. However, the extent of their identification, reduction, and removal is the subject of cost/benefit analysis in terms of technical tractability and economics.

[SOURCE: ISO 3534-2:2006, 2.2.5]

4 Symbols and abbreviated terms

4.1 Symbols

n subgroup size

p proportion or fraction of units

R subgroup range

 R_{moving} moving range

 \overline{R} average of subgroup ranges

 $\overline{R}_{\rm moving}$ —average of subgroup moving ranges

s subgroup standard deviation

 \overline{s} average of subgroup standard deviations

X individual value

 $U_{\mathrm{CL}_{\overline{v}}}$ upper control limit for means

 $L_{\operatorname{CL}_{\overline{X}}}$ lower control limit for means

 $U_{\mathrm{CL}_{\mathbf{Y}}}$ upper control limit for individual value

 $L_{\mathrm{CL_{Y}}}$ lower control limit for individual value

 $U_{\rm CL_p}$ upper control limit for ranges

 $L_{\mathrm{CL}_{R}}$ lower control limit for ranges

 $U_{\mathrm{WL}_{\overline{\mathbf{v}}}}$ upper warning limit for means

 $L_{
m WL}$ lower warning limit for means

 $U_{\rm WL}$ apper warning limit for individual value

 $L_{\mathrm{WL}_{v}}$ lower warning limit for individual value

 \overline{X} average of subgroup individual values

NOTE In International Standards, abbreviated terms can contain multiple letters, whereas symbols consist only of a single letter. The reason for this is to avoid misinterpretation of compound letters as an indication of multiplication, in formulae.

7

4.2 Abbreviated terms

CUSUM Cumulative sum

EWMA Exponentially weighted moving average

FMEA Failure mode and effects analysis

SPC Statistical process control

5 Concepts

5.1 Control chart

The control chart is a graphical display of data from the process, which allows a visual assessment of the process variability and stability. At defined intervals, subgroups of items of a specified size are obtained and the value of a characteristic or feature of the items is determined. The data obtained are typically summarized through the use of appropriate statistics and it is these statistics that are plotted on the control chart. A typical control chart will consist of a centre line that reflects the level around which the plotted statistic can be expected to vary. In addition, this control chart will have two lines, called control limits, placed one on each side of the centre line that define a band within which the statistic can be expected to lie randomly if the process is in control (see Annex A).

The two control limits are used as a criterion for judging the state of control of a process. The limits define a band, the width of which is determined in part by the inherent variability of the process. If the chosen statistic plots within the band, the chart is indicating that the process is in a state of statistical control and hence the process is allowed to continue operating as it is currently configured. However, a value of the statistic plotting outside the control limits indicates that the process can be "out of control". The control chart is then providing a signal suggesting that a special cause of variability can be present and consequently there is a need for action on the process.

Actions that can be taken on the process consist of

- a) undertaking an investigation to determine the source(s) of a special cause(s), with a view to elimination, correction, or reduction of the effect of such cause(s) in the future,
- b) making a process adjustment,
- c) continuing the process on a risk assessment basis,
- d) stopping the processor taking containment action until correction has been made, and
- e) retaining the special cause, making it permanent whenever possible in cases where special cause indications are of a positive nature (e.g. process improvement).

Sometimes, a second set of limits called "warning limits" is also placed on the control chart. The observation of a plotted point falling outside the warning limits but not outside the control limits indicates that, although no "action" is required on the process, increased attention should be paid to the process since a suspicion has been raised that a special cause might have affected the process. It might prove advantageous to then shorten the interval of time to the next sample and/or to increase the size of the next sample in order to more quickly determine if the process has undergone a change. When warning limits are included on the control chart, the control limits are then sometimes called "action limits".

Optionally, additional rules used for judging the state of control of a process take various forms, such as data points within limits but exhibiting unusual patterns. These rules, often called "decision rules" or "test rules," are defined in ISO 7870-2 along with their associated pattern tests.

When the objective is that of process acceptance, additional limit(s), called acceptance limit(s), might be needed as a decision criterion to judge the process acceptability. See <u>5.3</u>. Acceptance control charts are defined in ISO 7870-3.

5.2 Statistical control of a process

Control charts are often used to judge the stability of a process. A process is considered to be in a "state of statistical control" (the process is effectively said to be "in statistical control") if it is affected by random (or common, or chance) causes only, i.e. if no extraordinary, unexpected, or special (or assignable) causes have entered the system. Such special causes can affect either the level at which the process is operating, the degree of variability around the process level, or both simultaneously.

Variations due to random or chance causes occur in a random fashion and are usually found to obey certain statistical laws. In essence, when a process is "in statistical control", it is possible to predict reliably the behaviour of that process, whereas when special (or assignable) causes enter the system, the process is subject to the results of these causes and the outcome cannot be predicted without information about their presence and effect. A process found not to be in a state of statistical control is said to be "out of control" and requires intervention to bring it into such a state. For certain economic or natural phenomena, there might be no known way to intervene and the control chart simply serves to identify a lack of control.

5.3 Acceptance of a process

In addition to monitoring the stability of the process, control charts can also be used to judge the acceptability of a process. When the process is in statistical control, it is then possible to determine, with controlled risks of decision errors, if the process output does or does not meet product or service requirements. This is most effective when the variability of the process is small compared to the tolerance defined by the specifications. In such situations, the process level can temporarily shift to an out-of-control state, yet all product and service requirements are still being met. The control chart is then used to maintain the acceptable status of the process, notwithstanding the dynamic nature of the process level. Specific control charts, as described in ISO 7870-3, are needed in this case.

5.4 Management of a process with a natural drift

When some irremovable disturbance causes the process level to drift, for example the concentration of a specific chemical in a batch, there can exist a compensatory variable that can be manipulated to adjust the level of the process. In this situation, specifically designed charts can be used to indicate when and by how much the process should be adjusted to compensate for the disturbance effects. This type of control often results in a significant reduction in the variability of the process. In particular, it guarantees that the process will not be adjusted more often than necessary (over-adjustment), which would instead increase the inherent variability.

5.5 Risks of decision errors

In judging the state of control of a process using a set of decision rules together with a limited sample of data points, two types of decision errors can be made.

The first type of error (type I error) is made when a plotted point results in the decision that the process is not in statistical control and action is required on the process; but the true situation is that the process is operating within a system of random causes. Hence, the process will have been erroneously declared to be "out of control". The risk of making this type of error is called the "alpha (α) risk".

The second type of error (type II error) results when a special cause affecting the process has occurred but the data from the process has not yet led to the decision being made that the process is "out of control". Until the control chart indicates otherwise, the process will erroneously be declared to be "in statistical control". The risk of making this type of error is called the "beta (β) risk".

To control the risk of these errors, control limits, sets of decision rules, and subgroup sizes can be appropriately chosen.

5.6 Design of data collection

5.6.1 General

The most important element of data collection is the selection of the characteristics to be studied and the identification of the place or stages of control. The way in which data are collected is of fundamental importance to the efficient operation of the control chart to discriminate effectively random against special causes. Based upon an understanding of the nature of the process and the data to be collected, careful consideration shall be given to how the samples or subgroups are to be defined, their appropriate subgroup sizes, and the frequency at which they are obtained.

5.6.2 Choice of characteristic

To start, a decision is taken with regard to the characteristics for which a control programme is desired. In choosing the characteristic, the following aspects are required. One is that the characteristic strongly reflects the state of process. The other is that the characteristic is related to assuring the quality characteristic of product. An example choosing the characteristic is demonstrated. Table 1 shows a subject matter for choosing the characteristic, which is based on the results of FMEA and process analysis. The higher the severity ranking of the product characteristic and the earlier in the process one is able to control it, the better. Considering Table 1, the roll pressure and the stress torque applied to hinge can be candidates for the characteristics of control charts.

Component Severity ranking **Product characteristic Process parameter** characteristics of (from FMEA table) examples examples the product 9 to 10, safety critical Thickness of an insulator Shaft diameter Roll pressure 5 to 8, significant Pitch diameter Stress torque applied Resistance to movement characteristic of the screw to hinge 2 to 4, others Surface texture Handling Scratches

Table 1 — Subject matter for choosing characteristics

5.6.3 Measurement process evaluation

Before implementing any type of process control activity, it is of crucial importance to ensure the validity of the measurement process. The variability induced by measurement (see ISO 22514-7) shall be estimated in order to check that it can adequately detect characteristics variation. In this context, choice of measurement (including method, device, etc.) needs to be capable with respect to specifications or to process variability.

5.6.4 Subgroup selection

Subgroups are samples of collected items obtained from the process in a defined manner. Data from characteristics of these items are determined from which statistics, such as a number of nonconformities or an average or a range, can be computed and plotted on the control chart.

Rational samples or subgroups should be selected in a manner that makes each subgroup as homogeneous as the process will permit. Within a rational subgroup, variation is presumed to be due only to random causes. These causes are sources of variation inherent in a process over time. Rational subgroups are selected to enable the detection of any special causes of variation between subgroups. Short-term variability is measured using the variability within a series of reasonably homogeneous subgroups and determines the position of the control limits on the control chart, while long-term variability is usually evaluated in terms of changes between subgroups. Time order is often a good basis for forming subgroups because it allows for detection of special causes that can occur over time.

However, other bases, such as the need to study operator-to-operator variability, machine-to-machine variability, or supplier-to-supplier variability, can suggest that subgroups be defined across operator, machine, or supplier instead of over time.

The rational subgroup should be subject to all usual sources of random cause variation if it is to have meaningful value. For example, a series of repeat readings on a piece of material set in a testing instrument will fail to include the contribution of locating the material in the instrument or of obtaining the sample. If these aspects were inherent in a usual testing environment, the repeat readings would give an unrealistic, low estimate of inherent measurement variability. Thus, almost any actual measurement from the process would appear to be "out of control".

5.6.5 Subgroup size

Subgroup size should be selected so as to balance the ability to detect small shifts in the process and the risk of not detecting special causes. A larger subgroup size, although more costly, will provide a more precise assessment of the process, therefore allowing for a more efficient monitoring. However, if the sample is too large, special causes have more opportunities to occur within the collection period of the sample, causing increased within-sample variation; hence, control limits might be unduly widened and many special causes can occur without detection.

When dealing with attributes data, the subgroup size needed to detect changes in the process proportion will ordinarily be very much larger than the subgroup size using variables data, since attributes data carry much less information than variables data.

In some situations, it is impractical, or it does not make sense, to form subgroups, but rather to collect information on individual units, so that, essentially, subgroup size is equal to one. This is the case when testing is destructive or sampling is costly, or when repeated measurements on the process (continuous or batch processes) differ only because of instrument or analysis error.

5.6.6 Sampling frequency

Sampling frequency is dependent upon the magnitude of the shift in the process that is considered to be crucial to detect in a timely fashion, as well as upon the cost of the process operating in an out-of-statistical-control state. The smaller the shift to be detected, the greater the number of samples, of a given size, that will need to be collected before a signal is detected on the chart. Shortening the period between which samples are taken will decrease the period before any process fault is detected, and in which the process might have operated in an out-of-control state and produced faulty product. However, in defining the period, cost considerations of sampling and testing can also be considered. Care should be taken to ensure that the period does not synchronize with parameters that can affect the process (e.g. always sampling at the start of the working period when temperatures are low, or every 50th product at the start of a raw material batch, or at a shift change).

5.7 Control charts for variables and attributes data

Control charts can be used for either "variables" or "attributes" data. Variables data represent observations obtained by measuring and recording the magnitude of the characteristic under study on a continuous scale of measurement. Attributes data represent (categorized or countable) observations obtained by noting the presence (or absence) or the frequency of occurrence of some characteristics in each of the items. A count is made of the number of units possessing the attribute or the frequency of occurrence of the characteristic on the item. Results are then expressed in terms of frequencies or proportions.

Fundamentally, control charts used for variables data (also called variables control charts) differ from control charts used for attributes data (also called attributes control charts) because of the different underlying distribution of the characteristic under study.

For most variables control charts, the normal distribution is generally assumed with observations being statistically independent. As a result of this assumption, two control charts are used for the dual purposes of controlling both the mean level or centre and the variability of the process. The first

involves a measure of location (centre) such as the sample average, median, or a single measured characteristic itself if the sample contains only one item. The second uses a measure of dispersion (variability) of observations within the sample, such as the sample standard deviation or the sample range, or the absolute difference between two consecutive observations if the sample contains only one item at a point in time. Both types of charts are required in order for the variables control chart approach to be effective.

The distance between control limits on the chart for location (average) is a function of the variation that is monitored on the chart for dispersion. It is therefore important in constructing the control chart for process level (average) to verify that the process is in statistical control with respect to its dispersion.

For most attributes control charts, either the binomial or the Poisson distribution is generally assumed. Each of these distributions has a single parameter that shall be monitored for stability of the process. Therefore, only a single chart is necessary for monitoring a process with attributes data. Because the standard deviation of the proportion or count can be estimated once the subgroup size is known and the proportion or count in the sample is determined, the control limits on the attributes chart can be determined.

6 Types of control charts

The system of control charts specified in this document is composed of those corresponding to the following process characteristics: "process stability" and "process acceptance".

When the purpose is to achieve or maintain process stability the Shewhart control chart (see ISO 7870-2) and the related control charts can be used.

When the purpose is to achieve process acceptance, acceptance control charts are used (see ISO 7870-3). However, ISO 7870-3 specifies that a preliminary Shewhart control chart study should be conducted to verify the validity of using an acceptance control chart. In addition, control of the process variability shall be maintained.

Some of the specific charts within these general types are described in <u>Clauses 7</u> and <u>8</u>.

In addition, there are statistical methods, described in <u>Clause 9</u>, which apply when it is not possible to bring or maintain the process in statistical control. These methods will predict process adjustments, the purpose being to keep the process as close as possible to target.

7 Charts for process stability

7.1 General

Two general forms of the Shewhart control chart exist.

The first is a control chart with no pre-specified control limits. This chart uses control limits based on the sample or subgroup data plotted on the chart. This form of control chart is used to determine whether the observed values of a series of samples vary by an amount greater than would be expected by chance alone. In essence, this type of chart is used to detect any lack of control particularly in the research and development stages, or in early pilot trials or initial production and service studies. This control chart is useful for assessing the variation of a new process, product, or service, including the variation of the measurement method. At this stage, caution shall be exercised in the interpretation of the signals on the chart since the control limits are functions of the plotted data.

The second is a control chart with specified control limits, based on adopted standard values applicable to the statistical measures plotted on the chart. The standard values can be based on

- a) prior representative data (such as that obtained from experience using control charts with no prespecified control limits),
- b) an economic value derived from consideration of needs of service and cost of production, or

c) a desired target value defined in a specification.

This form of control chart is used to monitor ongoing processes by assessing whether the observed measures for a sample value differ from the adopted standard values by an amount greater than should be expected by chance alone.

Preferably, the standard values should be determined as described in a) above because the transition from the first phase using a control chart with no pre-specified limits to the second phase where control charts are used with specified control limits requires continuity of the process control.

Note that the second form of control chart not only evaluates the constancy of the cause system, but also evaluates whether that cause system is properly located in terms of the adopted economic or target values.

7.2 Partial listing of Shewhart and related control charts

7.2.1 General

This listing is divided into three categories. The first two, based on independent observations, use data obtained either from each subgroup or accumulated from more than one subgroup. The third includes data for which the assumption of independence does not hold.

7.2.2 Charts using data from only one rational subgroup for each plotted value

7.2.2.1 Variables data

Charts which can be used for variables data from one rational subgroup for each plotted value include the following:

- a) \overline{X} and R control charts (average for measure of central tendency and range for measure of dispersion) or \overline{X} and s control charts (standard deviation replacing range). Median control charts can be substituted for the average control charts (ISO 7870-2);
- b) X and moving range control charts (see 7.2.3) (ISO 7870-8);
- c) multivariate charts (ISO 7870-7);
- d) trend control charts;
- e) high-low control charts;
- f) group control charts;
- g) control charts for coefficient of variation;
- h) Z and R control charts (ISO 7870-5 and ISO 7870-8).

Multivariate control charts are used to detect shifts in the mean or in the relationship (covariance) between several related characteristics. Typically only one summary statistic derived from the combination of the characteristics to be controlled is plotted on the chart.

7.2.2.2 Attributes data

Charts which can be used for attributes data from only one rational subgroup for each plotted value include the following:

- a) *p* charts (proportion or percent categorized units control charts);
- b) *np* charts (number of categorized units control charts);
- c) *c* charts (count control charts);

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- d) *u* charts (count per unit control charts);
- e) standardized p charts;
- f) demerit control charts:
- g) control charts for inspection by gauging;
- h) *X* and moving range control charts for counts or proportions.

7.2.3 Charts using data from more than one subgroup for each plotted value

7.2.3.1 Moving average control chart and moving range control chart with *X* control chart (see ISO 7870-5)

In some situations, individual observations are plotted on an X control chart. Moving ranges (differences between two consecutive observations) are then plotted on a moving range chart to estimate and control the variation displayed by the process. Sometimes, moving averages of each successive n observation can be used instead of X control charts.

7.2.3.2 Cumulative sum (CUSUM) control chart (see ISO 7870-4)

The cumulative sums of deviations of individual observations or subgroup summary statistics, such as \overline{x} , R, s, and p, from a reference value are plotted. The state of control of the process is determined through the use of a device known as a V-mask. This chart, because of the reinforcing carry-over effect, is usually more sensitive to small shifts in level than the ordinary Shewhart control chart. Equivalently, for cases when the objective is mainly to detect off-standard conditions, rather than to present a graphical summary of sequential data, a tabular CUSUM technique exists which does not require a chart, but is similar in its intended use. A numerical decision rule then replaces the V-mask. A useful feature of the CUSUM technique, whether graphical or tabular, is its ability to provide an estimate of the point at which a change to a process parameter might have occurred.

7.2.3.3 Exponentially weighted moving average (EWMA) charts (see ISO 7870-6)

Individual observations or subgroup averages or subgroup ranges or subgroup standard deviations from the current and all previous observations are averaged, but those taken at earlier times are given progressively smaller weights. Because of the reinforcing carry-over effect, this chart is more sensitive to small shifts, but less sensitive to large shifts than the Shewhart control chart.

7.2.4 Charts for non-independent (autocorrelated) observations

The assumptions that are usually cited in justifying the use of control charts for variable data are that the data generated by the process when it is in statistical control are normally and independently distributed with a fixed mean and a fixed standard deviation. An out-of-control condition is a change or shift in the mean or the standard deviation (or both) to some different value.

One of the most important assumptions made concerning control charts is that of independence of the observations. Conventional control charts do not work well if the data representing the quality characteristic exhibits even a low level of association over time, a phenomenon known as autocorrelation. Specifically, these control charts will give misleading results if the data are correlated. Unfortunately, the assumption of uncorrelated or independent observations is not even approximately satisfied in some manufacturing processes. One example would include chemical processes where consecutive measurements on process or product characteristics are often highly correlated. Another circumstance is where automated test and measurement procedures applied to every unit in time-ordered production has revealed the presence of autocorrelation.

One approach to deal with this type of autocorrelated process is simply to sample from the process data stream less frequently, such that the correlation structure in the sampled data becomes weak. The other is that the subgroup size is one. Although this seems to be an easy solution, it has the disadvantage